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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,642	10/06/2003	Henrik Bengtsson	6517.200-US	3938

7590 07/30/2008

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EXAMINER	
MACNEILL, ELIZABETH	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
07/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,642	BENGTSSON, HENRIK	
	Examiner	Art Unit	
	ELIZABETH R. MACNEILL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-25* is/are pending in the application.

4a) Of the above claim(s) *9-11,18-20,22,23 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12,14-17,21 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 June 2008 has been entered.

Election/Restrictions

1. Claims –11, 18-20, 22-23 and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 19 April 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-8, 12, 14-17, 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groth (US 2002/0020646) in view of Millerd (US 4,734,092)

Regarding claim 1, Groth teaches a needle device (Fig 1) comprising: a mounting surface (15) adapted for application to the skin of a subject, a plurality of needles (2), each needle comprising a distal pointed end adapted to penetrate the skin of the subject, wherein each needle has a first position (Fig 2) in which the distal end is retracted relative to the mounting surface, and a second position (Fig 3) in which the distal end projects from the mounting surface, the needles being arranged such that at least one needle can be moved from its first to its second position or from its second to its first position with at least one other needle not performing the same movement. Figs 1-4. Groth teaches a common fluid conduit member (neck and seal of the vial 9) having a fluid inlet (neck of the vial) adapted to receive fluid from a fluid source (vial 9).

Groth fails to teach adhesive means arranged on the mounting surface for adhering the needle device to the skin of the subject. Millard teaches adhesive means (20) used to secure the infusion device onto the skin of a patient in order to stabilize the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use adhesive means to stabilize the device of Groth onto the patient's skin.

Regarding claim 2, needle actuating means (3) are associated with a plurality of needles, the needle actuating means being operatable between a first actuating position and a second actuating position, whereby a first associated needle is moved from its first to its second position and a second associated needle is moved from its second to its first position.

Regarding claim 3, the needle actuating means are operatable between a plurality of actuating positions, each operation between actuating positions being associated with operation of a corresponding pair of needles between their first and second respectively second and first positions.

Regarding claim 4, the needle actuating means is operatable between an initial position, in which all associated needles are in their first position, and an actuating position, whereby a needle is moved from its first to its second position.

Regarding claim 5, the needle actuating means is operatable between an actuating position, in which an associated needle is in its second position, and an end position in which all associated needles are in their first position.

Regarding claim 6, each of the associated needles are connected to a needle carrier (3), the actuation means comprising moveable control means (6) in engagement with or operatable to come into engagement with the needle carriers, the position of the control means controlling operation of the needles between their respective first and/or second positions.

Regarding claim 7, the needle carriers are associated with biasing means (11, 7) for moving the respective needle from its first to its second position by a force generated by the biasing means, release of the biasing means being controlled by movement of the control means.

Regarding claim 8, the control means comprises a cam surface (6) with a sloped portion, whereby movement of the sloped portion causes a needle to be moved from its second to its first position against the force of the biasing means.

Regarding claim 12, the device comprises means (pawls on the pawls wheel, see Claim 11) preventing a needle from being moved from its first to its second position more than once.

Regarding claim 14, see Fig 9 showing only one needle in communication with the fluid conduit at a time.

Regarding claim 15, see vial 9

Regarding claim 16, see injection device 8

Regarding claim 17, see fluid inlet (seal of vial)

Regarding claim 21, the plurality of needles comprises at least two hollow infusion needles, the hollow infusion needles being arranged such that only one infusion needle can be positioned in the second position at a given time.

Regarding claim 24, see vial 9 and injection device/ expelling means 8

Response to Arguments

2. Applicant's arguments filed 25 June 2008 have been considered but are moot in view of the new ground(s) of rejection. In prior rejections, applicant had argued that Groth does not teach a common fluid conduit and that one of ordinary skill in the art would not apply an adhesive to Groth. Regarding the common fluid conduit, the examiner finds that the neck of the vial and the seal are a common fluid conduit for conducting fluid from the vial to the needle. As to the adhesive, Groth expressly teaches that his device is used for attaching needles to a vial for injection into the skin, especially for weak people or people with limited mobility. Placing an adhesive on the skin-facing surface of Groth would serve to stabilize the device on the skin and hold the

device in place if the user cannot perform the injection quickly and smoothly (i.e. shaking hands, fatigue). Therefore, one of ordinary skill in the art would have been motivated to apply an adhesive to Groth to improve its applications for weaker patients.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767